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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,436	04/17/2001	Xiaowu Liang	GTSYS.006A	5847

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,436

Applicant(s)

LIANG ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-57, 60-85 and 90-110 is/are rejected.
- 7) ☒ Claim(s) 58, 59, 86-89 and 111-114 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7/1403.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Notice of References Cited	Application/Control No. 09/836,436	Applicant(s)/Patent Under Reexamination LIANG ET AL.	
	Examiner Konstantina Katcheves	Art Unit 1636	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,527,674	06-1996	Guerra et al.	435/6
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Ausubel et al. Short Protocols in Molecular Biology 1999 pages 9-21 to 9-24 and 9-31 to 9-32.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

DETAILED ACTION

Claims 53-114 are pending in the present application. This Office action is in response to Applicant's amendment filed 30 June 2003.

Response to Amendment

Rejections of claims 1-52 are moot in view of Applicant's cancellation of these claims in the Amendment filed 30 June 2003.

Claims 53, 54, 60-76, 77-80, 82, 84, 85, 90, 92-95, 97-101, 103-105, 107, 109 and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Nature Genetics Vol.20 1998).

The rejection of claims 63-66 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's Amendment.

Response to Arguments

With regard to the rejections of claims 53, 54, 60-76, 77-80, 82, 84, 85, 90, 92-95, 97-101, 103-105, 107, 109 and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Nature Genetics Vol.20 1998), Applicant has argued (1) that Zhang et al. fail to teach that the vector is linear and (2) that the vector lacks a critical element of a selection marker. For the purposes of examination, claims are accorded their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Applicant's arguments are noted, however not found persuasive for the following reasons. First, Zhang et al. teach that their vector is linear. On page 1316 and in

figure 2a and figure 3b, Zhang et al. teach their cloning method with a linear vector, thus meeting this limitation of the claims. Applicant asserts that Zhang et al. does not teach the incorporation of a critical element of a selection marker into the target nucleic acid. Without further definition by Applicant, a critical element may include all or part of a selection marker such that given the breadth that the present claims cover, Zhang et al. also meets this limitation of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55, 56 and 57 rejected under 35 U.S.C. 102(b) as being anticipated by Guerra et al. (US Patent No. 5,527,674).

Guerra et al. teach a method wherein a negative selection system is used to establish whether homologous recombination occurred between a vector and a target nucleic acid. A positively selectable marker is situated in a region between a first and second flanking region homologous to sequences in a target nucleic acid. The negative selection element prevents expression of the positive selection element. Homologous recombinants survive exposure to the positive element. See abstract and column 4-5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 53-54, 60-85 and 90-110 rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. as applied to claims 53, 54, 60-76, 77-80, 82, 84, 85, 90, 92-95, 97-101, 103-105, 107, 109 and 110 above, and further in view of Ausubel et al. (Short Protocols in Molecular Biology).

Zhang et al. is relied upon as described above. Zhang et al., however, fail to teach the specific selectable markers of the claims.

It would have been obvious to one of ordinary skill in the art at the time that the invention was made to use various types of selectable markers in the claimed cloning method. The use of selectable markers including kan^r, amp^r, and other cite by applicant are germane to the art and within the purview of the ordinary skilled artisan. These markers have routinely been used in cloning methods such that one of ordinary skill in the art would have been motivated to use them

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in their cloning method. Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

Claims 58, 59, 86-89 and 111-114 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
September 25, 2003


REMY YUCEL, PH.D.
SUPERVISORY PATENT EXAMINER
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